IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| Serial No. | : | 10/734,671 |
| Appellant | : | Foerster et al. |
| Filed | : | 12/12/2003 |
| Group Art Unit: | | 3736 |
| Examiner | : | Hoekstra |
| Docket No. | : | DEV-897DIV3 |
| Customer No.: | | 021884 |
| Title | : | METHODS AND DEVICES FOR DEFINING AND MARKING TISSUE |

## APPEAL BRIEF

Mail Stop Appeal Brief - Patents
Commissioner of Patents and Trademarks
PO Box 1450
Alexandria, VA 22313-1450

Sir:

## REAL PARTY IN INTEREST

Devicor Medical Products, Inc. is the real party in interest in the above referenced patent application.

## RELATED APPEALS AND INTERFERENCES

Neither Appellants' representative, Appellants' assignee, nor Appellants are aware of any appeals and/or interferences effected by or having a bearing on the Board's decision in the pending appeal.

## STATUS OF CLAIMS

Claims 49 and 50 are currently pending. Claims 49 and 50 stand finally rejected. Appellants accordingly appeal the Examiner's Final Rejection of claims 49 and 50.

## STATUS OF AMENDMENTS

An After Final Amendment cancelling claims 51 and 52 is being filed herewith. As to the amendments filed prior to the Final Rejection, all amendments appear to have been entered and considered.

## SUMMARY OF THE CLAIMED SUBJECT MATTER

Claim 49 is the only independent claim involved in the present Appeal and claim 50 is the only dependent claim involved in the present Appeal. As such, claims 49 and 50 are summarized below.

Claim 49 claims a delivery system (10) for delivering marker material (12) to a target site (51) within a patient. The delivery system (10) includes an elongate member (54) having a distal end, a discharge port in the distal end and an inner lumen (56) extending therein to and in fluid communication with the discharge port in the distal end. A plurality of small radiodense markers (one or more 12i) are disposed within the inner lumen (56) and are deployed as a biopsy marker material. The delivery system (10) also includes an ejector (18, 24) which is advancable with and coupled to the elongate member (54). The ejector (18, 24) is configured to eject the biopsy marker material (12i) from the discharge port in the distal end of the elongate member (54) to mark a desired biopsy site for locating the biopsy site during a future examination. Support is found throughout the Specification as originally filed where the reference numerals listed above are used. Specification, Page 16, line 27, through Page 18, line 13 and Page 22, lines 20-28.

Claim 50 depends from claim 49 and further requires that the plurality of small radiodense markers are beads or pellets. Specification, Page 22, lines 22-27.

## GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether claims 49 and 50 stand properly rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 3,741,198 to Burton ("Burton").

## ARGUMENTS

### I. CLAIMS 49 AND 50 ARE NOT ANTICIPATED BY BURTON

Claim 49 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Burton. This rejection is improper and Appellants respectfully request it be reversed.

Claim 49 requires a delivery system for delivering marker material to a target site within a patient. The delivery system includes an elongate member having a distal end, a discharge port in the distal end and an inner lumen extending therein to and in fluid communication with the discharge port in the distal end. A plurality of small radiodense markers (one or more 12i) are disposed within the inner lumen and deployed as a biopsy marker material. The delivery system also includes an ejector which is advancable with and coupled to the elongate member. The ejector is configured to eject the biopsy marker material from the discharge port in the distal end of the elongate member to mark a desired biopsy site for locating the biopsy site during a future examination.

"Anticipation requires that each and every element of the claimed invention is described in a single reference". *AKZO N.V. v. United States Int'l. Trade Comm'n*, 808 F.2d 1471, 1479 (Fed. Cir. 1986). As will be explained below, Burton fails to disclose each and every limitation set forth in claims 49 and 50 and, therefore, fails to anticipate claims 49 and 50.

Prior to determining whether a single reference discloses each and every element of the claimed invention, the language of the claims must be interpreted. Although claims during examination are given their broadest reasonable interpretation in order to facilitate precision in claiming, that interpretation must be "consistent with the specification, [and] claim

language should be read in light of the specification as it would be interpreted by one of ordinary skill in the art". *In re Bond*, 910 F.2d 831, 833 (Fed. Cir. 1990); see also *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) ("[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question."); and *In re Gary Edward Wheeler*, Case No. 2008-1215 (CAFC 2008 (nonprecedential opinion)). Considering the Examiner's interpretation of the pending claims and the manner in which Burton reads upon the pending claims, it is Appellants' opinion the Examiner has gone well beyond the broadest reasonable interpretation.

When construing claims, the claims and the rest of the patent, along with the patent's prosecution history (together, the intrinsic evidence of the meaning of the claims) are the primary resources; while helpful, extrinsic sources like dictionaries and expert testimony cannot overcome more persuasive intrinsic evidence. See *Phillips v. AWH Corp.*, 415 Fed 3rd at 1318.

Considering whether the Examiner has properly interpreted the language of the claims and then whether the properly defined terms have been applied to the pending claims in accordance with the patent laws, Appellants respectfully believe the Examiner has erred. With regard to the limitations relating to a "biopsy site", the Examiner suggests it is reasonable to interpret that the site in the spinal column at which the marking fluid of Burton is injected can reasonably be interpreted as a biopsy site. To quote the Examiner,

> the Examiner notes the claims and limitations therein are being treated on the merits with the broadest reasonable interpretation thereof consistent with the instant specification. The term 'biopsy site' may be reasonably interpreted with its plain meaning to include 'a position, location, or setting for the diagnostic study of tissue of a living body'. Burton clearly discloses the

> deployment and injection of radiographic ferrofluid for radiological diagnosis of abnormalities, including for example tumors. The 'desired biopsy site' is the spinal column site where the marking fluid is injected. For example, when a tumor is found this may be considered a 'biopsy site' as broadly as claimed. (underline added for emphasis)

Somehow one is to believe that injecting ferrofluid into the spinal column, moving it up and down to image the spinal column, removing the ferrofluid and determining from these images that a tumor exists as disclosed by Burton reads upon injecting a biopsy marker into a desired biopsy site.

The Examiner's interpretation of the term "biopsy site" is not reasonable, is beyond the scope of Appellants' specification, and is inconsistent with the meaning that one of ordinary skill in the art would apply. The meaning of a "biopsy" is well defined and understood in the medical field. Regardless of the source from which the definition for "biopsy" is taken, a "biopsy" requires the removal of tissue, cells or fluid from the body. The Examiner has interpreted "biopsy site" without reference to the fact the precursor to a "biopsy site" is the performance of a "biopsy". That is, and as used in the present claims in a manner understood by one of ordinary skill in the art and explained in detail in the Specification, in order to have a "biopsy site" one must first perform a "biopsy". "Biopsy" is a well defined and understood term in the medical field and it is beyond a reasonable interpretation to suggest that any old spot chosen on the spinal column is a biopsy site and locating a tumor is the same as a biopsy site. The Specification on Page 1 recites examples of a "biopsy", for example, 1) "Open biopsy removes the entire mass (excisional biopsy) or a part of the mass (incisional biopsy)", and 2) "The chief difference between FNA and core biopsy is the size of the tissue sample taken".

With regard to the term "biopsy marker material", the Examiner suggests a plain meaning includes "a substance of which a thing is composed that is used as an indication for the diagnostic study of tissue of a living body". The Examiner cites no source for this interpretation (presumably because the Examiner's interpretation is not that of one skilled in the art, but of one whose sole intention is the creation of a rejection). Appellants have thoroughly considered the definition suggested by the Examiner and are not sure how the interpretation set forth by the Examiner has anything to do with a material that is used to mark a biopsy site. Further, the Examiner's interpretation is not understood by Appellants or Appellants' representative, nor is it believed that one of ordinary skill in the art would understand the interpretation being suggested by the Examiner. Once again, it is commonly understood, by all in and out of the medical field, that a "biopsy marker" is something used to mark the location of a "biopsy", i.e., the taking of tissue. As set forth in the instant Specification, that is the disclosure upon which a reasonable interpretation is to be based, a "biopsy" requires the removal of tissue or cells and then marking the site of the removed tissue such that the marked site can be relocated at a later time.

Burton neither explicitly nor inherently discloses all of the structural limitations claimed. Claim 49 requires a plurality of small radiodense markers deployed as a biopsy marker material and disposed within the inner lumen of the delivery system. This structural limitation is not disclosed by Burton. Burton cannot possibly disclose a biopsy marker material since no biopsy is taking place in Burton (Burton rather injects ferrofluid into the spinal column). As discussed above, a biopsy requires the removal of tissue and a biopsy marker is used to mark the area from which the tissue is taken, such that the area can be

relocated if needed. Without a biopsy there can be no biopsy site or biopsy marker. To propose that injecting a ferrofluid into the spinal column of a patient has anything to do with a biopsy is unsupported by the disclosure of Burton as well as any reasonable interpretation of one of ordinary skill in the art.

The ferrofluid of Burton does not mark a desired biopsy site for locating the biopsy site during a future examination as required by the claims. The ferrofluid is free to travel up and down the spinal column and does not function to mark a site in which tissue, cells or fluid have been removed from the body. If a biopsy marker was free to move in the body once inserted, the movement would be contrary to the intended purpose of the biopsy marker and the marker would fail to function as a biopsy marker as a medical professional would not be able to locate the desired biopsy site. Surely, the terms of Appellants' claims must be given more weight than injecting any substance into a body and then imaging the substance.

Burton discloses a radiopaque ferrofluid, which is injected to increase the radiopaqueness of body systems where there is slow flow of fluids, to permit radiological examinations by creating a contrast during X-ray procedures. In particular, the ferrofluid of Burton is injected into the spinal column and then is moved up and down the spinal column via a magnetic force to desired areas along the spinal column while taking radiographic images of the desired areas. A highly important aspect of Burton is once the radiographic examination is completed the ferrofluid is removed. The ability to completely remove the ferrofluid and thereby avoiding patient discomfort is Burton's advancement over the prior art. As such, it is evident the ferrofluid of Burton is not used to mark a desired site for locating a biopsy site during a future examination and thus does not function as a biopsy marker as

claimed. Once again, the term "future examination" has meaning in the art and one of ordinary skill understands that when taking a biopsy and marking the biopsy site that examination in the future is not during the same procedure. The biopsy taken actually has to be tested before there is a need to locate the biopsy marker in a future examination. Burton's ferrofluid may be used to image the spinal column during the same procedure, but it surely cannot function to locate the spot at which it was injected since it is removed at the end of the imaging procedure.

With the forgoing in mind, Burton fails to disclose each and every limitation of claim 49 and thus is improperly relied upon as anticipating claim 49 under 35 U.S.C. § 102 rejection.

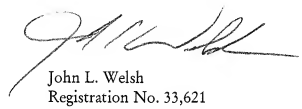
Turning to claim 50, Burton merely discloses a ferrofluid including a mass of particles. However, claim 50 require beads or pellets, not a mass of particles. The Examiner in a previous Office Action, dated November 7, 2008, stated the language "a mass of solid particulate marker material" was not supported by Appellants' specification, however, "a plurality of small beads or pellets" was supported. As such, and according to the Examiner, beads or pellets are not a mass of particles. Therefore, how can the Examiner now propose Burton anticipates Appellants' claim? Are we now to understand that a mass of particles is the same as a plurality of beads or pellets?

With the forgoing in mind, Burton fails to disclose each and every limitation of claim 50 and thus is improperly relied upon as anticipating claim 49 under 35 U.S.C. § 102 rejection.

## II. CONCLUSION

In conclusion, Appellants have now shown that the rejection of claims 49 and 50 under 35 U.S.C. § 102 is improper. Therefore, it is respectfully requested that the outstanding rejection of claims 49 and 50 be reversed.

Respectfully submitted,



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## CLAIMS APPENDIX

49. A delivery system for delivering biopsy marker material to a biopsy site within a patient, comprising:

an elongate member having a distal end, a discharge port in the distal end and an inner lumen extending therein to and in fluid communication with the discharge port in the distal end;

a plurality of small radiodense markers deployed as a biopsy marker material and disposed within the inner lumen; and

an ejector which is advancable with and coupled to said elongate member and which is configured to eject the biopsy marker material from the discharge port in said distal end of said elongate member to mark a desired biopsy site for locating the biopsy site during a future examination.

50. The delivery system for delivering biopsy marker material of claim 49, wherein the plurality of small radiodense markers are beads or pellets.

## EVIDENCE APPENDIX

Not Applicable

## RELATED PROCEEDINGS APPENDIX

Not Applicable